Product claims 1-7 directed to the femur endoprosthesis have been rewritten as new claims 9-17, inserting the features agreed to at the interview and removing non-essential, but preferred, features to claims 11 and 14. In addition, method claim 8 has been rewritten as new claim 18, with non-essential, but preferred, features being removed to dependent claims 19 and 20.

In order to provide antecedent basis for the terms used in the claim amendments, a new paragraph has been added at page 5 of the specification to describe and label with reference numerals the anatomical parts of the femur bone which are shown in the sole Figure of drawings. These parts of the femur bone are well recognized by one skilled in the art, as shown, for example, by the attached figure from a standard German anatomy textbook, namely *Anatomie des Menschen* (Anatomy of Humans). In the Figure at the top of page 8 of this reference, ref. no. 1 shows the metaphysial region ("Metaphyse") and ref. no. 6 shows the diaphysial region ("Diaphyse"). Ref. nos. 12 and 13 designate the greater and lesser trochanters, respectively ("Trochanter major" and "Trochanter minor"). In addition, the transition of the stem into the caudally bent stem end has been labeled and described as step 31 for ease of reference in the claims. These features and reference numerals have been labeled in a marked-up copy of the drawings as a proposed drawing amendment in the accompanying Letter to the Official Draftsman. Since all of these features are shown in the original drawing and are merely being named and labeled as would be readily recognized by one skilled in the art, it is submitted that no new matter is being added.

Further, in reviewing the application, it was noted that the portion of the endoprosthesis inserted in the femur was referred to at pages 3-5, as well as in the claims and abstract, as a "shell," whereas in the discussion of the prior art in the Background section of the application, the portion of the endoprosthesis inserted in the femur is referred to as a "stem." It appears that the term "shell" was carried over from German Patent 196 01 340 which describes a hollow sleeve or shell (German "Hülse") over which the present invention is an improvement (see top of page 5 of original specification). However, it is clear from the Figure of drawings in the present application that the portion of the endoprosthesis inserted in the femur need not be hollow, except to the extent that a conical sleeve 10 is used for receiving and holding the adapter 2 for attachment of the artificial spherical joint part 20. Therefore, it is believed that the term

"shell" may be misleading, and the specification has therefore been amended to use instead the term "stem" as used in the Background section of the specification. This insertion portion of the endoprosthesis is variously referred to in the art as a stem, a shank or a shaft, and any of these terms could have been used, but the term stem was used since it already appears in the present application.

Finally, for purposes of simplification, the primes have been removed from the reference numerals in both the specification and the Figure of drawings, and a substitute specification has been submitted for ease of entry of the various amendments discussed above. The substitute specification does not include claims, since all of the original claims have now been cancelled in favor of the new claims submitted herewith. As required by Patent Office rules, a marked-up (here black-lined) copy of the specification, showing the changes and additions made in the substitute specification, is also submitted herewith. No new matter has been added by these amendments, and entry of the substitute specification is respectfully requested.

At the interview, Professor Thomas, an orthopedic surgeon, explained and demonstrated the advantages of the femur endoprosthesis of the present invention by showing a plastic-encased longitudinal section (similar to the Figure of drawings in the present application) of a femur endoprosthesis of the present invention implanted in a cadaver femur, as well as two colored density X-rays showing the increase in bone density under the step of the endoprosthesis three and six months after implantation of the endoprosthesis of the present invention in a living femur bone. Professor Thomas explained that this caudally oriented step in the transition region of the endoprosthesis stem as it bends caudally into the stem end serves to resist further penetration of the stem into the medullary canal of the femur during the useful life of the endoprosthesis after implantation in the femur. The spike-shaped endoprosthesis stems of the prior art which do not have this step feature tend to progressively sink or press further into the medullary canal during the lifetime of the implant. Moreover, this feature allows the stem to be implanted in the metaphysial region of the femur, i.e., between the greater and lesser trochanters, whereas most spike-shaped stems of prior art endoprostheses extend well into the diaphysial region of the femur, i.e., below the lesser trochanter, thus requiring further resection of bone tissue for the implant. Further, unlike German Patent 196 01 340, implanting the endoprosthesis

of the present invention in the metaphysial region does not require an additional plate or a screw or bolt which penetrates the cortex of the femur, so that the strength of the metaphysial region and cortex is maintained.

Still further, with the endoprosthesis of the present invention, the femural neck or epiphysial region of the femural bone above the greater trochanter may be at least partially conserved or preserved, as shown in the Figure of drawings. This is in contrast to the prosthesis of the Morrey, et al. patent relied upon by the Examiner in rejecting the previous claims. Enclosed is a copy of a brochure illustrating the MAYO® Conservative Hip Prosthesis sold by Zimmer, Inc., which appears to be the hip prosthesis of the Morrey, et al. patent. As described in the insertion instructions in this brochure, a femural neck osteotomy must first be performed to resect the femural head and remove the neck or epiphysial portion above the greater and lesser trochanters. Such a resection or osteotomy is not necessary when implanting the femur endoprosthesis of the present invention.

Further, since the prosthesis of the present invention requires very little resection of natural bone material (see page 3, lines 19-20 of the specification), not only is natural bone tissue conserved to provide greater strength, but further revision surgeries become possible or more feasible after the useful life of the prosthesis. Thus, sufficient natural bone material will remain to accommodate a larger prosthesis in the next implantation. Hence, the prosthesis of the present invention is particularly advantageous in the case of patients who must undergo an implant at a relatively early age and are likely to require one or more additional implants later in life.

At the interview, both Examiners indicated that they were not aware of any prior art which uses a caudally oriented step in the transition area of the caudally bent distal end of the prosthesis stem, as in the presently claimed invention. Certainly, none of the prior art relied upon in rejecting the claims in the Office Action dated December 29, 1999 teaches or suggests such a step. Therefore, for the above reasons, it is submitted that the rejections of December 29, 1999 are not applicable to the present claims, and reconsideration and withdrawal are respectfully requested.

In view of the above amendments and remarks, it is submitted that all of the claims presently pending in the application patentably distinguish over all of the prior art of

record and known to applicants, either alone or in combination. Accordingly, reconsideration and an early Notice of Allowance are respectfully requested.

## CLARIFICATION RE: INFORMATION DISCLOSURE STATEMENTS

In reviewing the file, the following discrepancies were noted with respect to Information Disclosure Statements and prior art cited and considered by the Examiner. Clarification and consideration by the Examiner are respectfully requested.

(1) On July 15, 1999, applicants submitted an Information Disclosure Statement (received by the PTO on July 19, 1999), enclosing the Search Report from the counterpart European patent application and the prior art references cited therein. It is noted that the Examiner did not initial and return the PTO-1449 form indicating consideration of that prior art with the last Office Action. If that Information Disclosure Statement was not matched up with the file, the Examiner is requested to contact the undersigned and another copy will be sent.

(2) On July 22, 1998, applicants filed an Information Disclosure Statement (received by the PTO on July 24, 1998), submitting the Office Action from the counterpart German patent application and the prior art cited therein. In the Office Action dated June 23, 1999, the Examiner returned the PTO-1449 form from that Information Disclosure Statement with the French reference crossed out, but with no indication why the French reference was not considered. If the Examiner's reason for not considering this reference is that it is in the French language without an English language translation, that reason is insufficient, because the pertinence of the reference to the present application is already discussed at page 3 of the specification, and an English translation of the German Office Action in which the reference was cited was provided with the Information Disclosure Statement of July 22, 1998. Therefore, consideration of the French reference by the Examiner is required and respectfully requested. For the Examiner's convenience, the French reference has been provided again and listed again on the PTO-1449 form submitted with the enclosed new Information Disclosure Statement.

(3) In the Office Action of December 29, 1999, the Examiner included a new PTO-892 form listing essentially the same prior art as the PTO-892 form included in the Office Action of June 23, 1999, but adding a European reference of Calderale, et al. and deleting a U.S. Patent of Frey. It is not understood why the Frey reference was deleted, since it was apparently

already considered previously. Therefore, that reference has also been added to the PTO-1449 form in the enclosed new Information Disclosure Statement.

(4) In the Information Disclosure Statement submitted September 23, 1999, submitting the Office Action from the counterpart Japanese patent application and the prior art cited therein, it is noted that two of the Japanese application numbers are preceded by the designation "PCT," but it is not clear whether the counterpart PCT applications were submitted. Accordingly, they are submitted herewith in the accompanying new Information Disclosure Statement and listed by their English language PCT publications.

(5) In reviewing the application file, it was noted that several of the prior art references cited and discussed at pages 1-3 of the application have not been submitted in an Information Disclosure Statement. Accordingly, to the extent that these references have not already been submitted and may not have been considered, they are being submitted for consideration in the accompanying new Information Disclosure Statement. To the extent that these references are in non-English languages, their pertinence to the present invention is discussed in the Background section of the present application. Accordingly, consideration of the references and initialing and return of the PTO-1449 form are respectfully requested.

Respectfully submitted,

**HANS GRUNDEI, ET AL.**

April 17, 2000 By: William W. Schwarze

(Date)

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WWS/sc
Enclosures: 1998 Brochure of Zimmer, Inc. Re: MAYO® Conservative Hip Prosthesis
Cover and page 8 of *Anatomie des Menschen* (3rd Ed.)